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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,697	08/14/2002	Ajay Kumar Luthra	2177.26US01	8586
63274 7590 07/23/2009 DARDI & ASSOCIATES, PLLC 220 S. 6TH ST. SUITE 2000, U.S. BANK PLAZA MINNEAPOLIS, MN 55402				
EXAMINER				
YOUNG, MICAH PAUL				
ART UNIT		PAPER NUMBER		
1618				
MAIL DATE		DELIVERY MODE		
07/23/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/980,697

Applicant(s)

LUTHRA ET AL.

Examiner

MICAH-PAUL YOUNG

Art Unit

1618

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-67 is/are pending in the application.
- 4a) Of the above claim(s) 44-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-43, 66 and 67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/IC)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date: _____

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of claims 39-43, 66 and 67 in the reply filed on 4/30/09 is acknowledged. The traversal is on the ground(s) that the claims have been previously searched together and would not represent a burden. This is not found persuasive because the separate inventions remain distinct. The product of claims 39-43, 66 and 67 can be made by several methods including polymerizing a monomer with a pendant biguanide or by attaching a biguanide to a polymerized monomer. The methods of the separate groups would not necessarily result in the product of the chosen group.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 39-43, 66 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Olstein et al (USPN 5,142,010 hereafter '010) in view of Solomon et al (USPN 5,451,424 hereafter '424) and Ikeda et al, *New Polymeric Biocides...*, Aug. 1984, vol. 26, no.2, p. 139-144. The claims are drawn to a polymeric device with pendant biguanide groups. The medical device can include ocular lenses.

The '010 patent teaches a polymeric biguanide formulation where one of the nitrogen atoms is bond by an amine linkage (col. 2, lin. 15-65). The polymer formed is infection resistant and is useful in bulk polymers and copolymers (col. 3, lin. 49-65). The polymeric material is incorporated into various forms useful in or on the human body and as a coating, or an implantable medical device (col. 4, lin. 54-65; col. 13, lin. 21-36). The reaction sites binding to the polymer include isocyanate (col. 2, lin. 56-60). The polymers are subsequently blended with other polymers such as acrylic acid derivatives and methacrylate derivatives (col. 9, lin. 50-65). The formation of the polymer requires a polymerization process (col. 10, lin. 51-68). The process includes the incorporation of a carbodiimide (Example III). The polymers are combined with polymers useful for ocular lenses such as silicones (col. 12, lin.20-25). The reference is silent to the specific biguanide compound useful in making the biocidal polymers, however various biguanide compounds are well known to those of ordinary skill in the art. These compounds can be found in the '424 patent.

The '424 patent discloses a biguanide polymer comprising chlorhexidine (abstract). The biguanide is bound to polyurethane and used for medical tubing (example 1). Polyurethane is one of the many polymers used in grafting the biguanides of the '010 patent, therefore a skilled artisan would be motivated to include the biguanides of the '424 into the preparation of the '010.

The combination is silent to the tertiary amine groups being bound to a biguanide residue, however the combination of provides a biocidal polymer using the same compounds as the instant claims. Tertiary amino groups would be expected in charged biguanide compounds such as chlorhexidine or polyhexanide. Chlorhexidine is the biguanide used in the '424 patent. It would have been obvious to combine the specific biguanide compound of the '424 into the polymers of the '010 since each reference teaches similar polymeric structures and uses. The tertiary amine groups would be an inherent by product of the polymerization process. The '010 patent provides a method of making biocidal polymeric compounds comprising the combination of biguanide compounds with polymeric structures where the bonds occur at isocyanate reactive sites along the polymer chain, and carbodiimide coupling agents are used. According to the specification a partial free base must be formed when using chlorhexidine or polyhexanide, thus this step is also obviously be taken by one of ordinary skill in the art follow the teachings and suggestions of the prior art combination.

Regarding the specific linkages, although the '010 patent discloses that phenylene linkages would be useful in the production of the biocidal polymer; any linkage would be useful (col. 7, lin. 8-10). Secondary amine linkages have been known for use in biocidal polymers containing pendant biguanides as seen in the Ikeda study (Figure 1). The Ikeda study discloses new biocidal polymeric compounds comprising pendent biguanides that are linked using secondary amines such as piperidine rings (abstract, Figure 1). It would have been obvious to include these linkages into the polymer of the '010 patent in order to provide more polymerization options and a more stable polymer.

With these things in mind it would have been obvious to combine the teaching and suggestions of the art in order to provide a stable composition useful in treating a wide variety of bacterial infections. It would have been obvious to combine the process the bis(biguanide) of the '424 patent by the process of the '010 patent in order to provide a stable coating formulation. The patents share similar compounds and can be used in the ocular procedures. It would have been have been obvious to combine this compound with the '424 patent in order to arrive at a specific medical device. It would have been obvious to combine the linkers of the Ikeda study into the combination in order to improve the stability of the polymer, with an expected result of an infection resistant polymer useful in ocular devices.

Response to Arguments

Applicant's arguments with respect to claims 39-43, 66 and 67 have been considered but are moot in view of the new ground(s) of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 7:00-4:30; every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618